

NOV 16 2001

Special 510(k) Summary of Safety and Effectiveness:
Line Extension to the Long Length Gamma® Nail System

K013468

Submission Information

Name and Address of the Sponsor of the 510(k) Submission: Howmedica Osteonics Corp
59 Route 17
Allendale, NJ 07401-1677

Contact Person: Karen Ariemma
Regulatory Affairs Specialist

Date of Summary Preparation: October 17, 2001

Device Identification

Proprietary Name: Long Length Dyax Nail (formerly the Long Length Gamma® Nail System)

Common Name: Intramedullary Nail

Classification Name and Reference: Intramedullary Fixation Rod, 21 CFR §888.3020

This Special 510(k) submission is intended to address a material modification and design modifications to the predicate Long Length Gamma® Nail System. The subject device, named the Long Length Dyax Nail System, is a line extension of the Long Length Gamma® Nail System. The predicate Long Length Gamma® Nail System is fabricated from stainless steel. The subject Long Length Dyax Nail System is fabricated from titanium alloy. The design change for the nail involves changing the proximal diameter, changing the distal screw hole diameters and distal hole configuration and adding additional lengths of nails. The 5 mm diameter fully threaded locking screws from the T2 Nail System will be compatible with the Long Length Dyax Nails.

The predicate Long Length Gamma® Nail is an intramedullary rod intended to be used in the fixation of femoral fractures¹ occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intercondylar notch. The predicate design is cannulated, with a medial/lateral and anterior/posterior curve.

There is no change in intended use for the modified device when compared to the previously cleared product. The subject Long Length Dyax Nails are substantially equivalent to the existing design of Long Length Gamma® Nails which were determined substantially equivalent via the 510(k) process.

¹ Historically, Howmedica Osteonics has intended this product to be used in fracture management as a result of trauma, non-unions, mal-unions, pathological fractures, and impending pathological fractures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2001

Ms. Karen Ariemma
Regulatory Affairs Department
Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401

Re: K013468
Trade/Device Name: Howmedica Long Length Dyax Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 17, 2001
Received: October 18, 2001

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

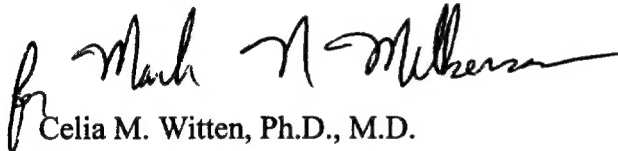
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

NOV 16 2001

Page 1 of 1

510(k) Number (if known): K 01 3468

Device Name: Long Length Dyax Nail System (line extension to the Long Length Gamma® Nail System)

Indications For Use:

The product is intended to be used in fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intracondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, mal-union, pathological fractures, and impending pathological fractures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

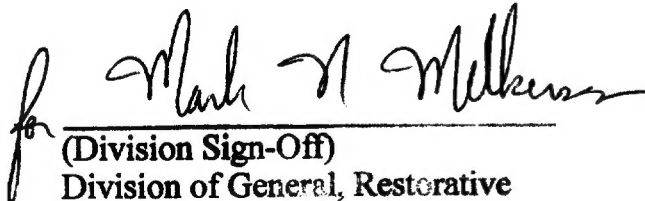
Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)


(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K 01 3468